

NOTES

SAME PILL, DIFFERENT PRICE: THE CASE FOR POLICY REFORM IN THE UNITED STATES BASED ON PHARMACEUTICALS' ACCESS STRATEGIES IN INTERNATIONAL MARKETS

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INTRODUCTION

Cien pesos, por favor. For approximately five U.S. dollars¹, anyone can walk out of a pharmacy in Mexico with a week’s worth of pills.² And in many cases, these same pills are manufactured in the United States (“U.S.”) and then packaged in Mexico.³ The only difference is the price. Generally, drug prices in international markets are significantly less than prices in the U.S.⁴ For example, a pill of the

1. *USD to MXN Exchange Rate*, BLOOMBERG, <https://www.bloomberg.com/quote/USDMXN:CUR> (last visited June 21, 2018).

2. See Kerry Ann Baker, *Drug Costs in the U.S. vs. Mexico*, VENTANAS MEX. (Jan. 26, 2019, 12:05 PM), <https://www.ventanasmexico.com/new-page-4/> (assessing the average cost in Mexico for the exact same medicine that is available in the U.S.); see also INFOGRAPHIC: *Prescription Drug Cost Comparison, the U.S. v. Abroad*, INT’L LIVING (Jan. 26, 2019, 12:45 PM), <https://internationalliving.com/prescription-drug-cost-comparison-the-u-s-v-abroad/>.

3. Baker, *supra* note 2.

4. See Ben Hirschler, *How the U.S. Pays 3 Times More for Drugs*, SCI. AM., <https://www.scientificamerican.com/article/how-the-u-s-pays-3-times-more-for-drugs/> (last visited Mar. 30, 2019) (reporting on research showing that U.S. prices were consistently higher than those found in European markets, and that U.S. prices “were six times higher than in Brazil and 16 times higher than the average in the lowest-price country, which was usually India.”); see also Erin Alberty, *To fight high drug prices, Utah will pay for public employees to go fill prescriptions in Mexico*, SALT LAKE TRIB. (Oct. 28, 2018), <https://www.sltrib.com/news/2018/10/28/fight-high-drug-prices/> (reporting the price disparity between drugs found in the U.S. and Mexico and, as one example, noting that Avonex, a drug which treats Multiple

popular erectile dysfunction drug Viagra is 15\$ U.S. dollars in a Tijuana pharmacy⁵ compared to \$92 U.S. dollars in a San Diego pharmacy.⁶ In addition, the same innovative drug found in U.S. pharmacies may have multiple different brand names in other countries, helping to expand access to patients from all socioeconomic backgrounds.

There is near unanimity amongst Americans that drug prices are out of control; innovative medicines can be far too costly for the average person. And in their search for solutions, Republicans and Democrats alike understandably focus most of their attention on the mechanics of the U.S. healthcare system. An unintended consequence of this narrow focus is that less attention is paid to potential solutions in international markets where the same drugs sold in the U.S. are often priced as much as 80% less. The problem of drug pricing in the U.S. is not merely a matter of industry lobbyists having inordinately strong power. Rather, the stark differences in pricing between U.S. and international markets is better explained by the structural differences between countries' healthcare systems, laws, and regulations.

For example, U.S. federal law requires Medicare⁷ and Medicaid to reimburse most FDA-approved drugs—and this impacts the government's overall expenditures on healthcare if no health-outcomes are required as a condition of reimbursement.⁸ Often, this system pushes up healthcare expenditures because the cost of reimbursing these new drugs exceeds the cost of treating the disease.⁹ In contrast,

Sclerosis, costs about \$4,500 less in Mexico); Bram Sable-Smith, *U.S. versus \$600 in Mexico. But is it legal?*, KAISER HEALTH NEWS (Feb. 12, 2019), <https://khn.org/news/americans-cross-border-into-mexico-to-buy-insulin-at-a-fraction-of-u-s-cost/> (reporting that a three-month supply of insulin to treat a child's diabetes would cost \$600 in Mexico, but the same supply would cost \$3,700 in the U.S.).

5. Interview with Pharmacist, Meds 4 Less Pharmacy, in Tijuana, Mex. (Oct. 28, 2018) (on file with author).

6. Interview with Pharmacist, Walgreens, in Encinitas, Cal. (Nov. 12, 2018) (on file with author).

7. See Paige Winfield Cunningham, *Here's why it's difficult to lower U.S. drug prices*, WASH. POST (May 4, 2018), <https://www.washingtonpost.com> (arguing that Medicare coverage accounts for less than 15% of the U.S. population and it is for the elderly and disabled).

8. See 42 U.S.C. § 1395w-104(b)(3)(G)(iv) (2017).

9. See generally Nisarg A. Patel, *Fee-for-Value in the Pharmaceutical Industry: A Policy Framework Applying Data Science to Negotiate Drug Prices*, J.L.

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most European countries have requirements for national reimbursement coverage.¹⁰ For example, the United Kingdom (“U.K.”) model imposes health-outcome requirements on manufacturers; they must demonstrate the economic benefit of new drugs to be eligible for national reimbursement consideration.¹¹

Countries also vary regarding their private sector coverage of drugs. The U.S. private sector’s tiered pricing structure of healthcare insurance drives pharmaceutical pricing and patient access to innovative medicines, and some states impose coverage mandates for a particular class of drugs.¹² However, internationally, private sector insurance coverage requirements vary based on that country’s healthcare model.¹³

In many international markets, the most innovative drugs are paid in cash by consumers; this triggers supply and demand mechanisms that impact patient access.¹⁴ Consequently, a company cannot charge more than the market can bear. For example, patients pay out-of-pocket for their medications in most emerging markets.¹⁵ Therefore, innovative

BIOSCIENCES 205, 206 (2017), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5570706/pdf/lx002.pdf>; see also Lee B. Staley, Note, *A Drug’s Worth: Why Federal Law Makes it Hard to Pay for Pharmaceutical Performance*, 98 B.U. L. REV. 303, 304 (2018).

10. Rachel E. Sachs, *Delinking Reimbursement*, 102 MINN. L. REV. 2307, 2339 (2018) (discussing the pros and cons of delinking FDA approval to reimbursement along with lessons from other countries).

11. *Id.* at 2340.

12. *Id.* at 2319.

13. Dana O. Sarnak et al., *Paying for Prescription Drugs Around the World: Why is the U.S. an Outlier?*, THE COMMONWEALTH FUND (Oct. 17, 2:30 PM), https://www.commonwealthfund.org/sites/default/files/documents/___media_files_publications_issue_brief_2017_oct_sarnak_paying_for_rx_ib_v2.pdf.

14. See Patricia M. Danzon, *Affordability and Accessibility to Medicines in EMs: Differential Pricing is the Solution* ISBINSIGHT, Apr.–June 2016, at 1, <http://isbinsight.isb.edu/affordability-and-accessibility-to-medicines-in-ems-differential-pricing-is-the-solution/>; see also Rachel Howard, *Understanding Patient Willingness to Pay*, RES. PARTNERSHIP (Oct. 14, 2015), <https://www.researchpartnership.com/resources/2015/10/article-understanding-patient-willingness-to-pay/>.

15. See Howard, *supra* note 14; see also *Emerging Market Economy*, INVESTING ANSWERS, <https://investinganswers.com/financial-dictionary/world-markets/emerging-market-economy-1518> (last visited Sept. 22, 2018) (explaining

drugs are competitively priced in these countries, and companies adopt a multitude of inter and intra-country pricing strategies to optimize patient access.¹⁶

Drug manufacturers claim that their U.S. pricing practices are necessary to offset research and development (“R&D”) expenditures;¹⁷ in other words, these pricing practices are necessary to fuel innovation. But, this claim raises an important question: how can these same pharmaceutical companies that conduct business outside of the U.S. sell the same innovative pill abroad at different prices and still be highly profitable?

If the arguments against drug price controls are true, then the U.S. would be the most innovative country, given it predominately does not regulate pharmaceuticals prices.¹⁸ However, countries such as the U.K. and Canada dispel this argument because, although the drug prices in the U.K. and Canada are significantly less than in the U.S., its pharmaceutical industries continue to be highly profitable and innovate in their respective countries.¹⁹

The pharmaceutical industry has one of the highest profit margins of any industry, and this is essential for investors because it shows reinvesting capabilities²⁰ to sustain profitability growth.²¹ For example, in 2013, this industry’s average profit margin was around 20% with some global drug companies exceeding a 40% profit margin.²²

that an emerging market is a country with an economy that is progressing through rapid growth and industrialization).

16. See *infra* Part II.

17. Donald W. Light & Rebecca Warburten, *Demythologizing the High Costs of Pharmaceutical Research*, 6 *BIOsocieties* 34, 34–35 (2011).

18. Salomeh Keyhani et al., *U.S. Pharmaceutical Innovation in an International Context*, 100 *AM. J. PUB. HEALTH* 1075, 1078 (2010).

19. *Id.*

20. See Geri Stengel, *Profit is Nice. Margins are Even Better*, INTUIT QUICKBOOKS, <https://quickbooks.intuit.com/r/financial-management/profit-is-nice-margins-are-even-better/> (last visited Nov. 17, 2018) (emphasizing that profit margins positively impact reinvestment opportunities more than other measures of growth).

21. Richard Anderson, *Pharmaceutical industry gets high on fat profits*, BBC NEWS (Nov. 6, 2014), <https://www.bbc.com/news/business-28212223> (describing the pharmaceutical industry’s profit margins relative to other major industries).

22. *Id.*

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These margins are comparable to the banking industry and are two to three times greater than the auto, oil and gas, and media industries.²³

It is important to point out that the majority of the pharmaceutical industry's expenses are not from R&D.²⁴ Drug companies spend far more on marketing drugs—twice as much in some cases—than on developing them.²⁵ For example, global companies generally spend 20 to 30% of their revenue on sales and marketing expenditures compared to 10 to 20% on R&D.²⁶ Although U.S.-based multi-national companies are pursuing strategies to develop new drugs abroad,²⁷ committed R&D resources are well short of those devoted to sales and marketing efforts internationally.²⁸ Therefore, the U.S., home to much of the world's drug development, is paying the bill for the same innovative medicine found in pharmacies around the globe. In effect, this amounts to the U.S. subsidizing drug development for the nations of the world.

U.S.-based multinational companies are turning a profit in the international markets by deploying targeted commercial strategies and partnerships that expand patient access to innovative medicines.²⁹ Why are these strategies not employed in the U.S. market? Meaningful drug price reform efforts must consider the policies and practices outside the U.S. and how these policies can contribute to U.S. reform efforts towards patient access to innovative medicines.

Much ink has been spilled on the subject of U.S. drug pricing reform—a Google Scholar search on this topic yields close to 500,000 articles.³⁰ This Note, however, focuses on the drug pricing and policy models implemented internationally and highlights strategies published by leading authorities. In turn, this Note proposes that many of these

23. *See id.*

24. *Id.*

25. *Id.*

26. *Id.*

27. Guido Reger, *Internationalization of Research and Development in Pharmaceuticals*, in *CHANGING INNOVATION IN THE PHARMACEUTICAL INDUSTRY* 97, 97–98 (A. Jungmittag et al. eds., 2000).

28. *See* Anderson, *supra* note 21; *see also* Richard Levy, *The Role and Value of Pharmaceutical Marketing*, 3 *ARCHIVES FAM. MED.* 327, 330 (1994).

29. *See infra* Part II.

30. GOOGLE SCHOLAR, https://scholar.google.com/scholar?hl=en&as_sdt=0%2C5&q=U.S.+drug+price+reform&btnG= (last visited Aug. 1, 2018).

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international strategies and best practices should be an integral component to U.S. reform.

Part I of this Note provides an overview of pharmaceutical pricing laws and regulations in several countries. Part II examines various commercial strategies deployed in these countries and other international markets that result in the sale of the same pill found in the U.S. but at a significantly lower price. Part III proposes U.S. policy reform based on innovative practices and models in international markets. This Note concludes that for these reforms to be implemented, the government, manufacturers, and payers must unite around a common goal: access to innovative medicines for those in need while reducing the overall costs to U.S. consumers.

I. OVERVIEW OF PHARMACEUTICAL PRICING LAWS AND REGULATIONS

In general, the U.S. government does not regulate the pricing of pharmaceuticals purchased by commercial payers and consumers.³¹ The country's retail supply chains remain largely unregulated, and drug manufacturers implement coupon programs that help lower patients' out-of-pocket costs.³² However, these coupon tactics also cause patient insurance plans to pay a higher price for more-expensive drugs.³³

On the other hand, in international markets, there is generally some regulation of pharmaceutical pricing.³⁴ At present, there continues to be a debate about U.S. drug pricing, and there is much controversy around this topic because it is not new.³⁵ One of the primary focuses of this debate is the role of the middlemen.³⁶ But, the middlemen, such as

31. Daniel L. Wellington & Robin Adelstein, *2018 Getting the Deal Through: Pharmaceutical Antitrust United States*, in PHARMACEUTICAL ANTITRUST (Marta Giner Asins & Yann Anselin eds., Law Bus. Research 2018), Lexis (database updated 2018).

32. Cunningham, *supra* note 5.

33. *Id.*

34. *See infra* Part I, Sections A–F.

35. Sachs, *supra* note 10, at 2307–09.

36. Robert Pearl, *4 Regulations that Would Terrify U.S. Drug Companies Ahead of the U.S. 2018 Midterms*, FORBES (July 16, 2018, 7:51 AM), <https://www.forbes.com/sites/robertpearl/2018/07/16/drug-companies/#6dbe76ac1e41> (discussing the U.S. government's drug pricing reform idea to "take out the 'middlemen.'").

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pharmacy benefit managers (“PBM”) and insurers, are not the sole source of the drug pricing problem—the problem has many causes, and it is one that needs to be addressed by the government, manufacturers, insurers, and consumers. Although Congress has considered the issue and continues to debate the Affordable Care Act (“ACA”), there is no meaningful proposed national drug price reform bill likely to pass in the short-term.³⁷ However, state legislators are addressing this problem; thirty states put forth eighty drug pricing reform bills last year.³⁸ For example, Massachusetts is turning to clinical evidence of improved outcomes and economic savings for new drugs to receive coverage.³⁹

Despite increasing calls to regulate drug prices, critics claim that placing U.S. price controls on innovative medicines will confine R&D to discoveries.⁴⁰ In turn, they claim innovation will slow, and patients in need of breakthrough medicines around the world will suffer.⁴¹ However, innovative medicines are only useful if patients in need have access to them.

Internationally, innovative medicines are less expensive than they are in the U.S.⁴² And many of these drugs are covered in national healthcare plans.⁴³ These countries find ways to get medicines from the U.S. or elsewhere, and they establish prices that enable increased patient access. The next section of Part I examines several countries around the world addressing the question of whether drug prices are subject to regulatory control in those countries and if so, how they are regulated.

37. See Alex Thompson & Sarah Karlin-Smith, *Warren bill would get feds into generic drug manufacturing*, POLITICO (Dec. 17, 2018, 11:02 PM), <https://www.politico.com/story/2018/12/17/elizabeth-warren-bill-drug-manufacturing-prices-1067916> (discussing proposed drug pricing bills and the challenges); Jay Hancock, Opinion, *Everyone Wants to Reduce Drug Prices. So Why Can't We Do It?*, N.Y. TIMES (Jan. 19, 2019, 3:00 PM), <https://www.nytimes.com/2017/09/23/sunday-review/prescription-drugs-prices.html>.

38. Sachs, *supra* note 10, at 2347–48.

39. See *id.*

40. *Id.*

41. *Id.*

42. U.S. DEP'T OF HEALTH & HUMAN SERVICES, OFFICE OF THE ASSISTANT SEC'Y FOR PLANNING AND EVALUATION, COMPARISON OF U.S. AND INTERNATIONAL PRICES FOR TOP MEDICARE PART B DRUGS BY TOTAL EXPENDITURES 9, 14 (Oct. 25, 2018).

43. *Id.* at 5–6.

A. Canada – Price Regulations for Patented Drugs

Patented drug prices are regulated.⁴⁴ Canada's Patented Medicine Prices Review Board ("PMPRB") examines several key factors: (1) the new product's therapeutic advantage over other products; (2) drug prices in the same therapeutic class; and (3) reference prices in other countries.⁴⁵ Canada continues to evolve its pharmaceutical pricing regulations by assessing the same drugs sold in lower-priced countries while also steering towards pharmacoeconomic evaluations.⁴⁶ Therefore, Canada is moving in the direction of other countries by adopting drug price reforms such as international reference pricing and health outcome requirements.

B. Mexico - Moderate Drug Price Regulations

Mexico's drug prices are subject to limited regulatory control; only some drugs are regulated, and even still, the extent of the regulatory control is limited. The Coordinating Commission for the Negotiation of Prices of Medicines and Supplies for Health ("Commission") primarily oversees the negotiation of drug prices and related supplies.⁴⁷ The Commission's pricing scope focuses on single source⁴⁸ or patent-protected medicines.⁴⁹ However, this Commission lacks the authority

44. Kevin Ackhurst et al., *2018 Getting the Deal Through: Pharmaceutical Antitrust Canada*, in PHARMACEUTICAL ANTITRUST (Marta Giner Asins & Yann Anselin eds., Law Bus. Research 2018), Lexis (database updated 2018).

45. *Id.*

46. *See id.*; *see also Pharmacoeconomics*, NATURE.COM, <https://www.nature.com/subjects/pharmacoeconomics> (last visited Apr. 2, 2019) (defining pharmacoeconomics as "the scientific discipline concerned with the cost and value of drugs, often with the goal of optimizing the allocation of healthcare resources.").

47. Ricardo Arturo Pons Mestre et al., *2018 Getting The Deal Through: Pharmaceutical Antitrust United States*, in PHARMACEUTICAL ANTITRUST (Marta Giner Asins & Yann Anselin eds., Law Bus. Research 2018), Lexis (database updated 2018).

48. *Single Source Drug Law and Legal Definition*, U.S. LEGAL, <https://definitions.uslegal.com/s/single-source-drug/> (last visited Sept. 22, 2018) (explaining that a single source medicine refers to a drug produced under an original new drug application approved by the country's regulatory agency).

49. Mestre et al., *supra* note 47.

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to impose final prices.⁵⁰ Instead, the Commission either negotiates how specific products will be priced and sold to consumers or it negotiates prices with the manufacturer.⁵¹ For example, a manufacturer with a patented drug must justify its pricing changes before the Commission.⁵²

Mexico's private and public markets make access to affordable and innovative drugs possible. Because people generally pay for medicines out-of-pocket in the private market, pharmaceutical companies implement innovative commercial and pricing strategies causing the same pill sold in the U.S. to be significantly less expensive in Mexico.⁵³ In the public market, the government establishes competitive bidding procedures to drive prices down.⁵⁴ For innovative medicines, formulary access is health economics driven.⁵⁵ If companies want to place new products in the government formulary, they must prove the economic value of the products while also pricing them in most cases below U.S. prices.⁵⁶

C. Brazil – Categorized Drug Price Regulations

Brazil's private market price controls vary depending on the type of pharmaceutical product pursuing market registration. In the public market, the government establishes competitive bidding procedures to drive prices down.⁵⁷ For innovative medicines, formulary access is price-driven.⁵⁸ In 2003, Brazil's legislature defined rules for the pharmaceutical sector and created the Chamber of Drug Market

50. *Id.*

51. *Id.*

52. *Id.*

53. *See Baker, supra* note 2.

54. Cynthia Irene Osio Sanchez & Roberto Hernández Garcia, 2018 *Getting the Deal Through: Public Procurement Mexico*, in PUBLIC PROCUREMENT (Totis Kotsonis ed., Law Bus. Research 2018), Lexis (database updated 2018).

55. Pierre Moïse & Elizabeth Docteur, Org. for Econ. Co-operation & Dev. [OECD], *Pharmaceutical Pricing and Reimbursement Policies in Mexico* 19–20, (OECD Health Working Papers No. 25, Feb. 13, 2007), <https://dx.doi.org/10.1787/302355455158>.

56. *See id.*

57. *See id.* at 21.

58. *See id.* at 19–20.

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Regulation (“CMED”),⁵⁹ which sets drug prices according to criteria contained in six categories.⁶⁰ These categories and criteria are in the following table.⁶¹

59. Alexandre Ditzel Faraco et al., 2018 *Getting the Deal Through: Pharmaceutical Antitrust Brazil*, in PHARMACEUTICAL ANTITRUST (Marta Giner Asins & Yann Anselin eds., Law Bus. Research 2018), Lexis (database updated 2018).

60. Memorandum from The Daveler Group, Inc. on CMED Policies and Criteria for Price Control in Brazil to Orexigen Therapeutics, Inc. (May 23, 2016) [hereinafter The Daveler Group] (on file with author).

61. *Id.*

CHAMBER OF DRUG MARKET REGULATION'S CATEGORY
AND PRICING CRITERIA

Category	Criteria
I	New patent-protected drugs: Launch price set by external reference pricing, not to exceed the drug's lowest price in Australia, Canada, France, Greece, Italy, New Zealand, Portugal, Spain, the U.S., and the country of origin.
II	"Me-too" drugs: ⁶² Launch price established by cost minimization approach.
III	New presentation, in the same dosage form, of an already marketed drug: Launch price based on the average prices of already marketed drugs.
IV	New presentation, in a different dosage form, of an already marketed drug: Launch price not to exceed the average price, weighted by sales, of available presentations of the drug that have the same active ingredients, strength, and dosage.
V	New combination of active ingredients already available in Brazil: Launch price not to exceed the drug's lowest price in any of the Category I countries.
VI	Generic drugs: Launch price not to exceed 65% of the respective reference product's price.

CMED's categorized price regulation helps the government control drug prices. And despite these regulations, Brazil's growing industry and economy make the country a priority for companies to commercialize their products.

62. See *Medical Definition of Me-too Drug*, MEDICINENET, <https://www.medicinenet.com/script/main/art.asp?articlekey=33748> (last visited Sept. 22, 2018) (explaining that a me-too drug is a drug that is duplicative or very similar to already known drugs).

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D. India – Price Regulations for Formulary and Essential Drugs

The National Pharmaceutical Pricing Authority (“NPPA”) regulates drug prices.⁶³ The NPPA is governed under the Drug Price Control Order where scheduled medicines (government formulary drugs), including essential drugs,⁶⁴ have a ceiling retail price and are under regulatory control.⁶⁵ India’s government also establishes the ceiling retail price of any drug, scheduled or non-scheduled, or of a new drug if the country deems it is in the public interest.⁶⁶

E. South Korea – Price Regulations if Drug Reimbursed

The National Health Insurance (“NHI”) system reimburses most drugs.⁶⁷ Under this system, the NHI negotiates with the manufacturer and, based on the NHI’s standards, establishes the maximum reimbursement price (“MRP”).⁶⁸ The NHI governs any adjustments to the MRP, and its procedures are established by legislation.⁶⁹ All reimbursed drugs are regulated in Korea.⁷⁰

F. Turkey – Price Regulations Through Reference Drug Pricing

Turkey’s Ministry of Health holds legislative powers to issue pricing guidelines and establish regulations.⁷¹ The government implements reference pricing by benchmarking drug prices found in

63. Samar R. Gandhi et al., *2018 Getting the Deal Through: Pharmaceutical Antitrust India*, in PHARMACEUTICAL ANTITRUST (Marta Giner Asins & Yann Anselin eds., Law Bus. Research 2018), Lexis (database updated 2018).

64. *Id.*

65. *Id.*

66. *Id.*

67. Kyung Shik Roh et al., *2018 Getting the Deal Through: Pharmaceutical Antitrust Korea*, in PHARMACEUTICAL ANTITRUST (Marta Giner Asins & Yann Anselin eds., Law Bus. Research 2018), Lexis (database updated 2018).

68. *Id.*

69. *Id.*

70. *Id.*

71. Gönenç Gürkaynak & K. Korhan Yıldırım, *2018 Getting the Deal Through: Pharmaceutical Antitrust Turkey*, in PHARMACEUTICAL ANTITRUST (Marta Giner Asins & Yann Anselin eds., Law Bus. Research 2018), Lexis (database updated 2018).

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France, Greece, Italy, Portugal, and Spain.⁷² In turn, innovative pharmaceuticals sold in Turkey may not exceed the lowest reference country price.⁷³

G. United Kingdom – Price Regulations if Drug Reimbursed

Patient access to medicines is controlled jointly by U.K.’s National Health Services (“NHS”) and the National Institute for Health and Care Excellence (“NICE”).⁷⁴ NICE requires manufacturers to provide rigorous health outcome data, including pharmacoeconomics, before a new drug is granted clearance into formulary.⁷⁵ The U.K. controls drug prices through a Pharmaceutical Price Regulation Scheme (“PPRS”) or the parallel statutory scheme.⁷⁶ Under the PPRS protocol, pharmaceutical companies enter a risk-sharing model with the government where drug manufactures rebate to the government excess drug expenditures.⁷⁷ Manufacturers who do not participate in the PPRS scheme are subject to statutory requirements.⁷⁸ Under these requirements, the government must approve a new pharmaceutical product’s price along with any price increases.⁷⁹

H. Summary - Majority of Countries Instill Price Regulations

Most countries outside the U.S. impose drug price regulations, but the U.S. generally does not.⁸⁰ While drug price policies outside the

72. *Id.*

73. *Id.*

74. John Schmidt et al., 2018 *Getting the Deal Through: Pharmaceutical Antitrust United Kingdom*, in PHARMACEUTICAL ANTITRUST (Marta Giner Asins & Yann Anselin eds., Law Bus. Research 2018), Lexis (database updated 2018).

75. *Developing and updating local formularies*, NICE, <https://www.nice.org.uk/guidance/mpg1/chapter/recommendations#processes-for-selecting-medicines-to-be-considered-for-inclusion-in-the-local-formulary> (last visited Jan. 20, 2019) (overview of process for selecting of medicine into the local formulary).

76. Schmidt et al., *supra* note 74.

77. *Id.*

78. *Id.*

79. *Id.*

80. See Wellington & Adelstein, *supra* note 31.

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U.S. vary, most are driven by similar factors including but not limited to drug type, international reference pricing, and reimbursement.⁸¹

Although many other countries impose strict drug pricing regulations, pharmaceutical companies still manage to generate substantial profit. Part II of this Note examines various drug manufacturers' tactics that enable them to still turn a profit despite significantly discounted drug prices. The remainder of Part II highlights some leading literature on these strategies and this author's experience in implementing them.

II. COMMERCIAL STRATEGIES ABROAD

Various commercial strategies are deployed in countries outside the U.S. to sell the same drugs found in the U.S. but at significantly lower prices. Drug manufacturers' strategies focus on increasing market access to their drugs in large populations while still earning a profit. In doing so, pharmaceutical companies execute inter and intra-country differential pricing tactics and R&D partnership strategies.

A. *Inter-Country Differential Pricing Strategies*

In response to innovation and increasing patient access to drugs, the industry engages in inter-country differential pricing.⁸² Inter-country differential pricing occurs where a company sells a particular drug for one price in one country and then sells that same drug at a significantly different price in another country.⁸³ The World Health Organization supports this approach because it ensures greater access to innovative medicines in developing countries.⁸⁴

When manufacturers implement differential pricing strategies, they can increase patient access to life-saving pharmaceuticals by up to seven times—and these strategies do not prevent manufactures from

81. See Ackhurst et al., *supra* note 44.

82. Brianna Carignan, *Legalizing Importation of Prescription Drugs: The Economic Implications of the Pharmaceutical Market Access and Drug Safety Act of 2005*, 12 NEW ENG. J. INT'L & COMP. L. 161, 178 (2005).

83. See Quentin A. Palfrey, *Expanding Access to Medicines and Promoting Innovation: A Practical Approach*, 24GEO. J. POVERTY L. & POL'Y 161, 169–70 (2017) (discussing manufacturers international pricing strategies).

84. Carignan, *supra* note 82, at 179.

maintaining a strong profit margin.⁸⁵ For example, consumers in low-income countries buy drugs at or below the manufacturer's marginal cost which expands the patient-base of pharmaceutical companies. As a result, drug demand and production increases, which help manufacturers reduce their overall costs.⁸⁶ Countries' tiered pricing is customary where depending on the drug, companies charge a tier one country one price and a tier two country a different price.⁸⁷ Companies recoup any lost profit in the lower tier or developing countries by pricing the same drug at a premium in wealthy countries.⁸⁸ Consumers in high-income countries, such as the U.S., argue such differential pricing is unfair.⁸⁹ However, this pricing strategy merely provides advantages to consumers in poorer countries, such as emerging markets, to access innovative medicines.

B. Intra-Country Differential Pricing Strategies

Pharmaceutical manufacturers also deploy intra-country differential pricing strategies, particularly in emerging markets.⁹⁰ Intra-country differential pricing is when a company sells its drug at a certain price in one area or market segment of the country and then sells the same drug for a significantly different price in another area or market segment of the country.⁹¹

Pharmaceutical companies over the last several years have designated emerging markets as critical to their growth.⁹² With affluent populations and a growing middle class, these emerging markets are a

85. *Id.*

86. *Id.*

87. See Palfrey, *supra* note 83, at 169; see also *HIV and Aids: bad news for drug prices in middle-income countries*, GUARDIAN (July 22, 2011), <https://www.theguardian.com/global-development/2011/jul/22/hiv-aids-antiretroviral-drugs-pricing> (providing instances in which HIV drugs were offered at reduced prices in low and middle-income countries).

88. Carignan, *supra* note 82, at 179.

89. *Id.*

90. Palfrey, *supra* note 83, at 171.

91. Prashant Yadav, *Differential Pricing for Pharmaceuticals*, MIT-ZARAGOZA INT'L LOGISTICS PROGRAM, 42-43 (2010), https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/67672/diff-pcing-pharma.pdf

92. Palfrey, *supra* note 83, at 171.

focus for companies to accelerate market entry for innovative products and executing commercial strategies. For example, Brazil and India are emerging markets where drug manufacturers are investing significant resources.⁹³ These countries are becoming common second priority targets behind the first priority U.S. and Europe for pharmaceutical product launches.⁹⁴

Intra-country differential pricing helps to both maximize company profits and expand patient access to medicines.⁹⁵ However, one risk that emerges from this strategy is the possibility of physical arbitrage. Drug manufacturers implement multiple commercial strategies⁹⁶ to mitigate the physical arbitrage⁹⁷ risks. Common tactics in emerging markets include the use of different brand names and packaging to different channels that reach more people.⁹⁸ This approach is where one brand has the same trademark as marketed in the U.S. and is priced at a premium, and the other brand has a local trademark and is priced significantly lower.⁹⁹ For example, in Mexico, Farmacias de Similares markets its pharmacy chains with the slogan, “Lo Mismo Pero Mas Barato”¹⁰⁰ (the same but much cheaper), and it targets the country’s poor consumers by selling its own private label of a manufacturer’s

93. *Brazil, Russia, India, and China (BRIC) Becoming Popular Second Wave Targets, Recent Study Finds*, MKT. WIRED (May 10, 2017), <http://www.marketwired.com/press-release/brazil-russia-india-china-bric-becoming-popular-second-wave-targets-recent-study-finds-2215496.htm>.

94. *See id.*

95. *See* Palfrey, *supra* note 83, at 171; *see also* Yadav, *supra* note 91, at 43.

96. Palfrey, *supra* note 83, at 172.

97. Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets*, 5 YALE J. HEALTH POL’Y L. & ETHICS 193, 205–06 (2005) (explaining that arbitrage is the practice of taking advantage of price differences in two or more markets).

98. *See* Ram Subramanian & Rehnab Baqri, *Branding: When One is Not Enough*, PHARMAEXEC.COM (Feb. 3, 2016), <http://www.pharmexec.com/branding-when-one-not-enough> (discussing second brand strategy for pharmaceuticals particularly in emerging markets); *see also* Rutger Daems et al., *Global Framework for Differential Pricing of Pharmaceuticals* 21 (UNU-Merit Working Paper No. 2011-054), <https://www.merit.unu.edu/publications/working-papers/abstract/?id=4557>; Palfrey, *supra* note 83, at 173–74.

99. *See* Subramanian & Baqri, *supra* note 98.

100. FARMACIAS SIMILARES, <https://farmaciasdesimilares.com/#/> (last visited Aug. 2, 2018).

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innovative drug.¹⁰¹ In doing so, Farmacias de Similares dramatically reduces its private label drug prices compared to other pharmacy chains such as Farmacias Benavides, where the same drug will be sold under a brand name at a premium price to the wealthy consumer.¹⁰²

This intra-country differential pricing strategy works well in international markets where people predominately pay out-of-pocket because such innovative commercial practices increase patient access and manufacturers' profits.¹⁰³ Therefore, in those countries—where poor and wealthy people live side-by-side—intra-country differential pricing offers great promise.¹⁰⁴

C. Research and Development Strategies and Partnerships

Pharmaceutical companies are also expanding their R&D strategies through international partnerships to accelerate market approval for their innovative medicines both in the U.S. and abroad.¹⁰⁵ If manufacturers in the U.S. use foreign research data provided through these partnerships, it can shorten the time to bring new life-saving medicines to the U.S. market.¹⁰⁶ However, Congress requires the Food and Drug Administration (“FDA”) to oversee the safety and efficacy of drugs sold in the U.S.¹⁰⁷ The FDA must balance the benefit of innovative drugs coming to market faster through the use of foreign

101. See David Luhnnow, *Maker of Generics Adds Spice to Drug Business*, WALL STREET J., <https://www.wsj.com/articles/SB110833733909653530> (last updated Feb. 14, 2005, 12:01 AM).

102. See FARMACIAS BENAVIDES, <http://www.benavides.com.mx> (last visited Oct. 28, 2018).

103. Subramanian & Baqri, *supra* note 98.

104. Palfrey, *supra* note 83, at 194.

105. Michelle Palmer & Rathnam Chaguturu, *Academia-Pharma Partnerships for Novel Drug Discovery: Essential or Nice to Have?* 12 EXPERT OP. ON DRUG DISCOVERY 537, 538 (2017).

106. See *FDA's Legal Authority*, FDA, <https://www.fda.gov/AboutFDA/History/FOrgsHistory/EvolvingPowers/ucm593384.htm> (last visited Feb. 2, 2019).

107. See John J. Gorski, Comment, *An FDA-EEC Perspective on the International Acceptance of Foreign Clinical Data*, 21 CAL W. INT'L L.J. 329, 331–33 (1990); see also Premnath Shenoy, *Multi-Regional Clinical Trials and Global Drug Development*, PERSP. CLIN RES. 62 (Mar. 31, 2016), http://www.picronline.org/temp/PerspectClinRes7262-7532148_205521.pdf.

research data with its mission of ensuring safety and reliability.¹⁰⁸ While the FDA is tasked with striking an appropriate balance in this context, another factor the FDA should consider is that the economy is becoming increasingly globalized, and technological innovation is increasing in markets around the world. The U.S. must look beyond its borders for solutions to benefit its citizens. Global R&D partnerships that develop innovative and cost-effective solutions will better serve the needs of patients in the U.S. and abroad.

For example, pharmaceutical companies are becoming increasingly interested in biosimilars,¹⁰⁹ and international partnerships are forming around this mutual interest. These drugs provide access to twice as many patients because biosimilars are half of the price of the original drug.¹¹⁰ Further, biosimilars provide patient access to lifesaving drugs. Since these types of drugs are significantly less expensive, a company can expand its novel drug's global access while still earning a profit.¹¹¹ Internationally, biosimilars are in high demand and offer another strategy to achieve corporate business goals.¹¹²

Pharmaceutical innovation is also on the rise in emerging markets. For example, in India, companies are discovering new medicines using state-of-the-art technologies.¹¹³ Research and development partnerships are being formed to tap into the unique and large

108. See generally *Acceptance of Foreign Clinical Studies – Information Sheet*, FDA (Mar. 2012), <https://www.fda.gov/RegulatoryInformation/Guidances/ucm126426.htm> (last visited Feb. 3, 2019) (providing a review of the FDA's guidelines regarding foreign clinical studies).

109. See *Biosimilars and Interchangeable Products*, FDA <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm580419.htm#biosimilar> (last visited Sept. 22, 2018) (defining biosimilars as “a biological product that is highly similar to and has no clinically meaningful difference from an existing FDA-approved reference product.”).

110. Guy Martin, *Biocad goals go beyond putting Russian biotech on the map*, PHARMA LETTER (Nov. 29, 2016), <https://www.thepharmaletter.com/article/biocad-goals-go-beyond-putting-russian-biotech-on-the-map>.

111. *Id.*

112. Bruno Calo-Fernández & Juan Leonardo Martínez-Hurtado, *Biosimilars: Company Strategies to Capture Value from the Biologics Market*, 5 PHARMACEUTICALS 1393, 1400 (2012).

113. Kurt Stoeckli, *India and the future of life science innovation*, LIVEMINT (Dec. 29, 2017), <https://www.livemint.com/Opinion/DOiDi0nGhJvWUX1nFIHOrK/India-and-the-future-of-life-sciences-innovation.html>.

population which is unlocking India's biopharmaceutical potential.¹¹⁴ Similar strategies are used in Russia.¹¹⁵ This partnership approach reduces costs, increases access to innovative products, and helps expand patient access to life-saving treatments at affordable prices.¹¹⁶ Innovative biopharmaceutical companies around the world striving to accelerate innovation are now pursuing opportunities to do so internationally.¹¹⁷

D. Summary - Commercial Strategies Enable Access

Pharmaceutical drug price regulations do not necessarily hinder patient access to innovative medicines. Global companies are accustomed to overcoming market barriers by deploying inter and intra-country pricing strategies and other commercial tactics to gain effective market access. Partnerships will continue to be a win-win for governments, patients, and the industry. If such strategies are working abroad, surely the U.S. can reform its policies to harness these approaches. However, U.S. reform can only take place if the healthcare system is fundamentally transformed.

Part III of this Note assesses policy options, many based on international models, which serve to stimulate discussion on meaningful U.S. reform. These options include increasing value-effectiveness measures, reference-based pricing, enforcing competition law, and pharmaceutical arbitrage. Part III concludes by outlining the best practices internationally and proposing plausible strategies that should be adopted in the U.S. in light of these international practices.

114. *Id.*

115. Taylor Heyman, *Russia: a bright future for clinical trials?*, PHARMACEUTICAL TECH. (Feb. 3, 2019, 2:30 PM), <https://www.pharmaceutical-technology.com/features/featurerussia-a-bright-future-for-clinical-trials-4872809/>.

116. See Press Release, *The Challenges and Opportunities of a Foreign Drug Registration in Russia*, ARS PharmRussia Reveals, MKT. WATCH (Jan. 15, 2018, 7:45 AM), <https://www.marketwatch.com/press-release/the-challenges-and-opportunities-of-a-foreign-drug-registration-in-russia-ars-pharmrussia-reveals-2018-01-15>.

117. *Global Pharma continues to see potential in investing in R&D in India*, BIOSPECTRUM (July 4, 2017), <https://www.biospectrumindia.com/news/69/9197/global-pharma-continues-to-see-potential-in-investing-in-rd-in-india.html>.

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III. UNITED STATES POLICY REFORM

There are several ways that policy can be reformed in the U.S., but these reforms would require significant legislative and regulatory changes.¹¹⁸ An open-minded approach—examining both domestic and international strategies—is needed to address pharmaceutical pricing reform for innovative drugs in the U.S. To be sure, proponents and opponents exist for all of these options—and some of these areas of disagreement will be discussed below.

A. Value-Effectiveness Policies

Instilling value-effectiveness measures is one of the most important ways to increase effective competition among brand-name drugs.¹¹⁹ One example of a value-effectiveness measure is making regulatory approval of a new drug contingent on proving that the new medicine saves overall health care costs. Policy experts argue that enhancing government authority for these kinds of value assessments, broadening substitution laws, and using evidence-based formularies will help promote effective competition.¹²⁰ However, these policy changes will likely face challenges unless the government also institutes regulatory changes. That is because a new drug's market approval is currently not dependent on reducing health care costs.¹²¹

Currently, neither the FDA nor any U.S. government agency conditions approval of an innovative drug based on value or cost, and

118. See Aaron S. Kesselheim et al., *The High Costs of Prescription Drugs in the United States: Origins and Prospects for Reform*, 316 [J]AMA 858, 865–66 (2016); see also Eric Mershon & Ike Swetiltz, *Will Trump's Plans Bring Down Drug Prices?*, SCI. AM. (Feb. 3, 2019, 10:00 PM), <https://www.scientificamerican.com/article/will-trumps-plans-bring-down-drug-prices/>.

119. Jonathan J. Darrow & Aaron S. Kesselheim, *Policy Options Paper: Promoting Competition to Address Pharmaceutical Prices*, HEALTH AFF. 4 (Mar. 15, 2018), https://www.healthaffairs.org/doi/10.1377/hpb20180116.967310/listitem/HPP_2018_CMWF_02_W.pdf (reviewing policy interventions to address competition shortcomings for lowering drug prices).

120. *Id.* at 4–5.

121. See *id.* at 4; see also Randall S. Stafford et al., *New, But Not Improved? Incorporating Comparative-Effectiveness Information into FDA Labeling*, 361 NEW ENG. J. MED. 1230, 1230 (2009).

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past attempts to do so faced political opposition.¹²² However, in other wealthy countries—such as the U.K. and Germany—designated agencies exist to evaluate the value of a new drug before the drug gains market approval.¹²³

Payers have options for therapeutic substitutions to diminish high-price, low-value drugs.¹²⁴ However, for these alternatives to be possible, drug substitution laws in the U.S. require transitioning substitution authority from the physician to the pharmacy level.¹²⁵ Both regulatory and cultural changes are needed to bring about this change.

Some private payers in the U.S. are also turning to value-effectiveness policies; consequently, manufacturers need to incorporate value-effectiveness to gain formulary inclusion.¹²⁶ For example, one PBM provided its clients the option not to cover a new medicine launched in the market at a price higher than \$100,000 per quality-adjusted life-year (“QALY”).¹²⁷ That is, if the new drug’s launch price was over \$100,000 per QALY compared to the current standard of care to treat the same disease, the employer’s insurance plan might not offer that new drug to its employees.¹²⁸ In comparison, most medications in Europe are initially launched to produce effectiveness rated at \$50,000 per QALY.¹²⁹

Generally, the U.S. does not have any such value-effectiveness threshold programs. Launch prices of new drugs in the U.S. continue to go up each year, pushing costs per QALY into the \$300,000 to \$500,000 range—costs that are not sustainable in the U.S. health care

122. Darrow & Kesselheim, *supra* note 119, at 4.

123. *Id.*

124. *See id.* at 4–5.

125. *Id.*

126. Troyen Brennan & Surya Singh, *Why CVS is Giving Plans a New Tool to Target High Launch Prices*, HEALTH AFF. BLOG: CONSIDERING HEALTH SPENDING (Sept. 17, 2018), <https://www.healthaffairs.org/doi/10.1377/hblog20180913.862850/full/>.

127. *See generally Do you know what a QALY is, and how to calculate it?*, C.E.L. FOR PHARMA, <https://www.celforpharma.com/insight/do-you-know-what-qaly-and-how-calculate-it> (last visited Nov. 17, 2018) (defining QALY and presenting the calculation).

128. Brennan & Singh, *supra* note 126.

129. *Id.*

system.¹³⁰ Critics of these exorbitant costs argue that value-assessment thresholds must factor in several considerations and new drug prices need to reflect value.¹³¹ Nonetheless, a value-effectiveness threshold requiring manufacturers to give reasonable discounts from the start of market entry for their new drug deserves consideration.

B. International Reference Pricing

International reference pricing is another policy that can be adopted as part of efforts to reform U.S. drug pricing. As the name suggests, international reference pricing primarily involves setting drug prices based on the price of the same drug in other countries.¹³² It is well-established that reference pricing controls drug reimbursement expenditures by benchmarking the prices of identical or similar drugs which are considered interchangeable.¹³³ This pricing mechanism is increasing in popularity in many countries.¹³⁴ Government reimbursement of drugs in a system with reference pricing is based on the price of that same drug in other countries.¹³⁵ For example, in Brazil, innovative patent-protected drug launch prices are established by referencing Australia, Canada, France, Greece, Italy, New Zealand, Portugal, Spain, the U.S., as well as the country where the drug originated.¹³⁶ The lowest price of the new drug in any of these countries is the price established in Brazil.¹³⁷ Other countries such as Poland and Canada have successfully instituted reference pricing and experienced decreases in prescription drug spending.¹³⁸

130. *Id.*

131. Robert Dubois, *CVS to Restrict Patient Access Using Cost-Effectiveness: Too Much, Too Soon*, HEALTH AFF. BLOG: CONSIDERING HEALTH SPENDING (Sept. 17, 2018), <https://www.healthaffairs.org/doi/10.1377/hblog20180913.889578/full/>.

132. Marie Salter, Comment, *Reference Pricing: An Effective Model for the U.S. Pharmaceutical Industry?*, 35 NW. J. INT'L L. & BUS. 413, 416 (2015) (discussing the importance of international reference pricing).

133. *Id.* at 416–17.

134. *Id.* at 426.

135. *See id.* at 416.

136. *See* The Daveler Group, *supra* note 60.

137. *See id.*

138. Salter, *supra* note 132, at 421.

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On the other hand, reference pricing could have a negative impact on global research and development because the U.S. is the home to much of the world's innovative drug research.¹³⁹ Forcing drug prices down in the U.S. risks reducing profits which could cause a decrease in investments towards discovering breakthrough medicines. However, some evidence suggests that countries with reference pricing or other types of regulation innovate proportionally more than the U.S.¹⁴⁰ Therefore, reference pricing does not necessarily cause a decrease in investments toward new drug development, particularly when U.S. federal funding continues to play an integral role in new drug discoveries.¹⁴¹ Enacting reference pricing should be part of U.S. policy reform. In a globalized economy where such an approach has been demonstrably successful in other countries, there is no reason why this approach should not be adopted in the U.S. The overall positive effects on payers and consumers outweigh any adverse effects.¹⁴²

C. Competition Law

Competition law can also be used to restrict excessive drug pricing. For example, Canada and South Africa expressly identify charging an excessive price a competition law violation.¹⁴³ In these countries, companies are prohibited from selling drugs at excessive prices despite having a patent and a monopoly position.¹⁴⁴ However, U.S. antitrust jurisprudence continues to prevent the excessive pricing doctrine from being used mostly because of the rights of the patentee to recoup investment and sell at a price that the market will bear.¹⁴⁵

The United States Supreme Court has not endorsed the excessive pricing doctrine, but the Court has made clear that a holder of a patent

139. *Id.* at 433.

140. *Id.* at 434.

141. *Id.*

142. *Id.* at 438.

143. Frederick M. Abbott, *Excessive Pharmaceutical Prices and Competition Law: Doctrinal Development to Protect Public Health*, 6 U.C. IRVINE L. REV. 281, 298–99 (2016) (discussing competition law and policy to address excessive pharmaceutical drug pricing).

144. *Id.*

145. *Id.* at 319.

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that charges excessive pricing is not immune from antitrust laws.¹⁴⁶ Further, the Supreme Court of California puts the burden on the patentee to justify its pricing conduct.¹⁴⁷ Thus, competition law and enforcement of the excessive pricing doctrine should be used to constrain out-of-hand drug pricing when the patentee takes advantage of the U.S. free-market pricing system.

D. Pharmaceutical Arbitrage

Domestic intellectual property laws, reimbursement systems, and country-specific laws affect drug prices.¹⁴⁸ As a result, manufacturers establish differential pricing strategies across countries based on the socioeconomic status and pricing regulatory framework of each individual market.¹⁴⁹ It is well-documented that patented medicines in Canada are typically cheaper than the same medicine in the U.S.¹⁵⁰ For example, a patented drug sold for \$10 (U.S. dollars) in Canada may be identical to the same drug in the U.S. sold for a significantly higher price.¹⁵¹ Thus, lower-priced innovative drugs north of the U.S. border create consumer demand for cross-border parallel-trade or pharmaceutical arbitrage.¹⁵²

Drug imports from Canada are a textbook example of pharmaceutical arbitrage at work.¹⁵³ The practice started when U.S. citizens traveling to Canada for vacation or business needed to refill their U.S. prescription.¹⁵⁴ This practice evolved to U.S. citizens living close to the border embarking on trips for the specific purpose of

146. *FTC v. Actavis, Inc.*, 570 U.S. 136, 149-50 (2013).

147. *In re Cipro Cases I & II*, 348 P.3d 845, 867 (2015).

148. Outterson, *supra* note 97, at 195 (discussing pharmaceutical arbitrage impact on access and innovation and its implications on drug pricing and distribution).

149. For a detailed discussion of differential pricing, see Patricia M. Danzon, *Differential Pricing of Pharmaceuticals: Theory, Evidence, and Emerging Issues*, 36 PHARMACOECONOMICS 1395 (2018).

150. Outterson, *supra* note 97, at 195.

151. See *Average foreign-to-Canadian price ratio for patented drugs as of 2017*, STATISTA, <https://www.statista.com/statistics/496169/price-ratio-canadia-to-foreign-drug-prices/> (last visited Feb. 7, 2019).

152. Outterson, *supra* note 97, at 195.

153. *Id.* at 275.

154. *Id.* at 276.

obtaining lower-cost prescriptions.¹⁵⁵ This practice continued to spread—bus trips were organized for people living far away from the border, and a consumer market developed for mail order pharmacies to acquire patented medicines.¹⁵⁶

The internet greatly expanded the number of people engaging in cross-border arbitrage; the market jumped from the few million Americans living along the Canadian border to many millions of people throughout the U.S.¹⁵⁷ Despite the FDA's efforts to block attempts to acquire lower-cost patented drugs from Canada, consumers and institutions are saving hundreds of millions of dollars on patented medicines online with one click.¹⁵⁸

Despite these savings, federal and state actions continue to attack pharmaceutical arbitrage.¹⁵⁹ But healthcare public policy must champion access—and arbitrage encourages policy reform to take place which, in turn, will increase affordable access. Canada and other countries impose regulatory measures to restrict drug prices, which forces the U.S. to evaluate alternative regulatory systems.¹⁶⁰ Virtual arbitrage, or referencing other drug prices in other countries, also forces the government to assess prices in other countries. Moreover, virtual arbitrage is preferred to physical arbitrage because it is more resource-efficient and preserves the drug supply chain.¹⁶¹ As a result, the legislative branch is required to collaborate with the executive branch offices such as the Secretary of Health and Human Services (“HHS”) to enact laws and institute safe and cost-savings means to legalize the arbitrage process.¹⁶² Therefore, competitive analysis of the neighboring regulatory and pricing structures of other countries promotes reform.¹⁶³

In 2000, Congress passed the Medicine Equity and Drug Safety Act (“MEDS Act”), which permitted the importation of prescription drugs

155. *Id.*

156. *Id.*

157. *Id.*

158. *Id.* at 276–80.

159. *Id.* at 285.

160. *Id.* at 280–283.

161. *Id.*

162. *Id.* at 281.

163. *See id.* at 282.

originally produced in the U.S.¹⁶⁴ This law allowed the U.S. consumer to benefit from other lower priced medicines in other countries.¹⁶⁵ The following year, however, the HHS did not certify the MEDS Act, rendering it ineffective to concerns that pharmaceutical manufacturers still could keep prices at high levels.¹⁶⁶ U.S. policy reform should include re-assessing the MEDS Act and, if nothing else, adopting its mission to provide patients with alternative drugs at lower prices. The evolving global healthcare market over the last two decades justifies a re-assessment of this approach.

E. Best Practices Abroad

U.S. drug policy reform should also incorporate the best practices of other countries. In doing so, the U.S. healthcare system could evolve into universal coverage while still reducing overall healthcare expenditures. Many countries—including but not limited to Israel, South Korea, and Canada—have moved towards universal coverage while maintaining effective and efficient healthcare systems.¹⁶⁷ The following section will highlight several countries' best practices and discuss how those practices could become an integral part of U.S. drug policy reform.

1. Israel – Universal Healthcare Model

Healthcare spending in Israel as a share of gross domestic product (“GDP”) is 7.5%; the U.S., on the other hand, spends 16.4% of GDP on healthcare, and Israel enjoys a higher life expectancy than the U.S.¹⁶⁸ Israel employs seven strategies under its universal healthcare system to control drug prices.¹⁶⁹

164. Jonathan Ma, *Lowering Prescription Drug Prices in the United States: Are Reimportation and Internet Pharmacies the Answer?*, 15 S. CAL. INTERDISC. L.J. 345, 352 (2006) (discussing and reviewing the MEDS Act).

165. *Id.*

166. *Id.* at 352–53.

167. See generally Bruce Rosen, *Expanding Canadian Medicare to Include a National Pharmaceutical Benefit While Controlling Expenditures: Possible Lessons From Israel*, 13 HEALTH ECON. POL'Y & L., 324, 324–26 (2018) (reviewing Israel's strategies to constrain pharmaceutical spending); see also Roh et al., *supra* note 67.

168. Rosen, *supra* note 167, at 324–25.

169. *Id.* at 330–36.

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First, it prioritizes new technologies that are established by a governing board.¹⁷⁰ This prioritization process gives pharmaceutical companies crucial information regarding whether their new drugs will be included in the government program.¹⁷¹ In addition, risk-sharing agreements between the companies, government, and health plans help ensure access to novel medicines while controlling overall costs.¹⁷² Second, significant discounts are achieved through reference pricing implemented by the country's health plans.¹⁷³ Third, the pharmaceutical distribution system is efficient by capitalizing on economies of scale.¹⁷⁴ Fourth, measures are in place for physicians to avoid prescribing expensive drugs when less expensive alternatives exist.¹⁷⁵ Fifth, consumer drug advertising is regulated to avoid artificially inflating consumer demand.¹⁷⁶ Sixth, Israel strikes a balance between respecting intellectual property, access, and cost containment by strictly enforcing patents while at the same time creating a generics friendly environment.¹⁷⁷ Finally, Israel creates a shared societal understanding of the values of pharmaceuticals while aligning its citizens' expectations through its new health technologies prioritization process.¹⁷⁸

In summary, Israel's government plays an important and active role in its healthcare system. If U.S. policymakers seek to implement Israel's best practices, it would need to match this level of involvement in the U.S. healthcare system.

2. South Korea – Price Negotiation Model

The U.S. can also look to South Korea for solutions to its drug pricing problem. There, most drugs are reimbursed through the NHI.¹⁷⁹ If companies want their new medicines reimbursed, they must negotiate

170. *Id.* at 331–32.

171. *Id.* at 331.

172. *Id.* at 332.

173. *Id.* at 332–33.

174. *Id.* at 333.

175. *Id.* at 333–34.

176. *Id.* at 334.

177. *Id.* at 334–35.

178. *Id.* at 335.

179. Roh et al., *supra* note 67.

pricing with the NHI.¹⁸⁰ This process enables access to innovative drugs with built-in cost-containment measures.¹⁸¹ In comparison to the South Korean model, the U.S. government would need to establish linkage requirements between reimbursement and pricing of innovative medicines on a broader scale than what currently exists.

3. United Kingdom – Value-Based Model

In the U.S., FDA-approved drugs are often covered by insurance. For example, federal law requires Medicare and Medicaid to cover most, and in many cases all, FDA-approved drugs.¹⁸² Private payers have similar drug coverage tied to FDA approval due to federal and state laws.¹⁸³ This process enables access to innovative medicines, but it also creates cost-containment problems.¹⁸⁴

Importantly, the U.K.—one of the most studied drug price models—delinks drug approval and reimbursement.¹⁸⁵ Once the Medicines and Healthcare Products Regulatory Agency (“MHRA”) or the European Medicines Agency (“EMA”) approves a new drug, NICE examines the drug’s clinical and economic benefits and makes a recommendation to NHS regarding reimbursement.¹⁸⁶ This appraisal system causes almost all innovative drugs to be less expensive than those same innovative drugs covered in the U.S. public payer system such as Medicare.¹⁸⁷ Also, the U.K. encourages partnerships between NHS and pharmaceutical companies to develop new drugs for unmet medical needs.¹⁸⁸ For example, a Managed Access Agreement for cancer drugs establishes a framework where manufacturers know from

180. *Id.*

181. Seung-Lai Yoo et al., *Improving Patient Access to New Drugs in South Korea: Evaluation of the National Drug Formulary System*, 16 INT’L J. ENVTL. RES. & PUB. HEALTH 288, 290–92 (Jan. 29, 2019).

182. Sachs, *supra* note 10, at 2309.

183. *Id.* at 2311.

184. *See id.* at 2315, 2320–21.

185. *See id.* at 2339.

186. *Id.* at 2340.

187. *Id.*

188. *See id.* at 2341.

the beginning the additional clinical requirements for a new drug to receive a favorable NICE recommendation for reimbursement.¹⁸⁹

The U.K. model presses companies to demonstrate that new medicines have strong value. Specifically, it promotes innovation by delinking approval from reimbursement.¹⁹⁰ This model can help U.S. policymakers facilitate partnerships where innovation is encouraged and access is rewarded.

4. Latin America and Asia – Value-Based and Tendering Models

In some Latin American and Asian countries, new medicines and vaccines are subject to rigorous value-based assessments before they are considered for government formulary inclusion.¹⁹¹ These value assessments incentivize companies to price their products in these countries far below the price of the identical drug in the U.S.¹⁹² Thus, pharmaceutical manufacturers have a powerful incentive to offer drugs at affordable prices because they can gain access to the large population covered by government-funded national drug plans.¹⁹³

Public programs such as childhood immunizations implement tendering processes.¹⁹⁴ For example, many emerging markets institute a tendering model where the manufacturer offering the lowest price is granted country exclusivity to supply its vaccine for a given period of time.¹⁹⁵ Procurement mechanics vary in these markets resulting in

189. *Id.*

190. *See id.* at 2339–40.

191. *See Moise & Docteur, supra* note 55, at 19–20.

192. *See id.* at 30.

193. *See id.* at 17–18 (explaining that the IMSS, ISSSTE, and Seguro Popular de Salud cover approximately 100 million people in Mexico); *see also* Sang Cheol Seong et al., *Data Resource Profile: The National Health Information Database of the National Health Insurance Service in South Korea*, *INT’L J. EPIDEMIOLOGY* 1, 1 (2016) (highlighting that the NHI covers South Korea’s entire population of approximately 50 million).

194. *See* International AIDS Vaccine Initiative [IAVI], *Procurement and Pricing of New Vaccines for Developing Countries*, at 4, IAEA Pol’y Brief 16 (August 2008), http://www.rho.org/files/IAVI_vaccine_procurement_pricing.pdf.

195. *See* Nikolaos Maniadakis et al., *Shaping Pharmaceutical Tenders for Effectiveness and Sustainability in Countries with Expanding Healthcare Coverage*, 16 *APPLIED HEALTH ECON. & HEALTH POL’Y* 592, 592–94 (2018).

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some of the lowest available prices in the world.¹⁹⁶ However, in the U.S., the Centers for Disease Control (“CDC”) procurement process for childhood vaccines establishes in some cases dual suppliers to help ensure consistent supply of vaccines even when vaccine prices might increase from year to year.¹⁹⁷

F. Summary – Practical Policy Reform Options in the United States

The challenge for the U.S. in adopting the best practices discussed above is that currently, the U.S. has a fundamentally different healthcare system. Despite the challenges that will inevitably come with overhaul, policymakers should consider other countries’ models because they can produce meaningful reform. The U.S. should prioritize instituting reference-based pricing, promoting effective competition for innovation through a value-based regulatory and reimbursement system, and enforcing competition laws including the excessive pricing doctrine.

CONCLUSION

There is no question that given the problem of drug pricing in the U.S., reform is inevitable. But the devil is always in the details—the specifics of when and how this reform will be introduced, along with the reform’s impact, are open questions. Many countries have implemented reform measures which provide access to new and life-saving drugs at affordable costs.¹⁹⁸ Countries differ on approaches and there is no one-size-fits-all model that meets the needs of all markets.

Generally, most countries implement some form of drug pricing regulations. However, the U.S. is an exception with limited drug price regulations. These limited regulations drive up the cost of patented

196. Secretariat of the World Health Organization, *Global Vaccine Action Plan: Monitoring, Evaluation & Accountability Subchapter 4: Vaccine Price and Procurement Report 2017* 148, 152, https://www.who.int/immunization/global_vaccine_action_plan/gvap_2017_secretariat_report_vaccine_prices.pdf.

197. See *CDC Vaccine Price List*, CDC, <https://www.cdc.gov/vaccines/programs/vfc/awardees/vaccine-management/price-list/index.html> (last updated Mar. 1, 2019) (listing childhood vaccines and the suppliers of those vaccines).

198. See *supra* Part III Section E.

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innovative drugs to thousands of dollars per year, which results in many patients not having access to medicine developed in their own country.¹⁹⁹ However, this Note highlights that the very same pill sold in the U.S. will often be far less expensive abroad because of commercial strategies or government-imposed regulations, which can result in higher patient access.²⁰⁰ U.S. policymakers should examine these strategies, and others found to be successful internationally, while also leveraging its own best practices. In doing so, the U.S. can achieve drug pricing reform for the benefit of all its citizens.

199. See generally Patel, *supra* note 9, at 206.

200. See *supra* Part III Section E.

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Notwithstanding the policy reform issues that remain in the U.S., one thing is certain: meaningful change will happen when the government, manufacturers, and payers strive to achieve the common goal of access to innovative drugs for all those in need.

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